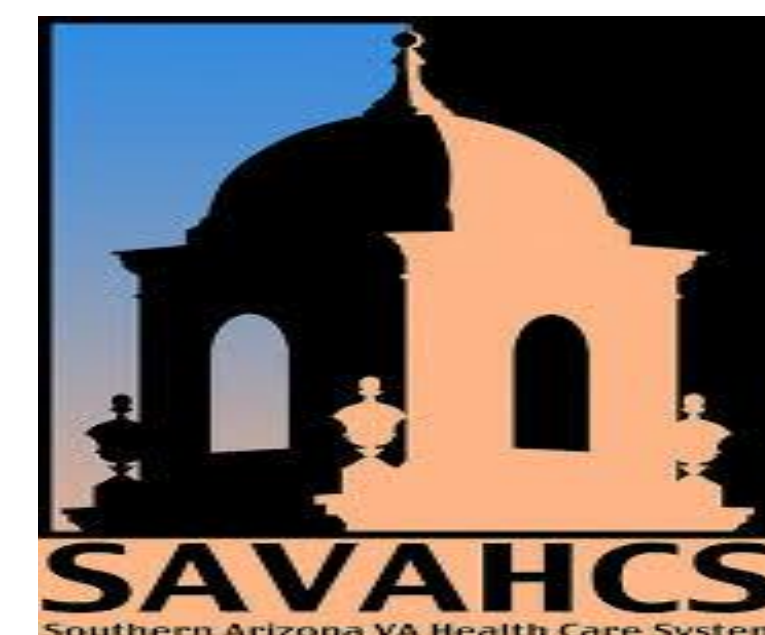




# Treatment of Post-Surgical Amputation Wounds of Diabetic Patients with Chorion-Free Amniotic Tissue Allografts: A Case Series

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## Introduction

Following diabetic amputations, patients can experience difficulty in healing their wounds and advanced biologics may be considered as a wound management strategy.

Amniotic membrane and fluid contain biologically active factors that play important role in wound healing process and tissue regeneration [1-7]. In this report, we present two cases of post-amputation wound management with chorion-free human amniotic tissue allografts.

## Material and Methods

We assessed the therapeutic potential of PalinGen® Hydromembrane, a chorion-free human amniotic allograft and/or PalinGen® Flow, a cryopreserved chorion-free liquid human amniotic allograft, in the treatment of postamputation wounds of two diabetic patients who developed nonhealing, infectious deep wounds overlying amputated toes.

PalinGen Hydromembrane® is packaged in a saline blue polymesh on both sides. Membrane is shelf stable and can be stored at room temperature (15° C-30° C). Periwound was prepped with benzoin tincture. The membrane was then separated from the polymesh and applied directly to the wound base. Membrane was secured and covered with mepitel and steristrips. SNaP® vac was utilized for case 2 and in both cases were covered with a sterile dressing over the mepitel and membrane.

## Case 1:

A 78-year-old type 2 diabetic male with peripheral neuropathy who presented to the ED with new onset foot infection of his right foot. Patient presented with pain, edema, drainage, and erythema to the midfoot, but no purulence or malodor. He was admitted to the hospital with fasting blood glucose of 449 and had elevated WBC of 13.7. Empiric Zosyn was initiated for cellulitis.

On initial exam, right foot plantar hallux ulceration was present. The ulcer measured 0.7 cm x 0.5 cm x 0.7 cm with central aspect probing deep to bone. There was concern for possible gas forming organism on x-ray imaging. Patient was consented for partial first ray amputation.

On post-operative day #2 proximal sutures were intact with a distal 2 cm portion of incision line open. Due to skin fragility and prior infectious process with tissue destruction, a chorion-free amniotic PalinGen® Hydromembrane was utilized for its antimicrobial and regenerative properties. The hydromembrane was placed over the dehisced surgical site with a non-adherent layer and dry sterile dressing.

On post operative day #7 a second Hydromembrane was applied in the same location. Marked reduction in edema and skin discoloration was noted. Patient was followed weekly in outpatient clinic. On post-operative day #21, the remaining wound measure 1.6 cm x 1.0 cm x 0.5 cm. Three more weekly applications of PalinGen® Hydromembrane were utilized, and there was continued decrease in depth and size of wound. Healing was accomplished by week 12.



Figure 1



Figure 2



Figure 3

**Figures 1-3:** 1: Post operative day #2, prior to application. 2: Post operative day #7. 3: Post operative day #30

## Case 2:

A 51 year old type 2 diabetic male with neuropathy with a history of left 3<sup>rd</sup> digit with gas gangrene, infection, and tissue necrosis and left 3<sup>rd</sup> and 4<sup>th</sup> digital amputations (2015, 2016) presented to the ED with a history of 3 month plantar ulceration with vomiting. Patient's WBC was elevated at 22.8. Patient was admitted to the hospital and immediate I&D was performed. Radiographs revealed gas formation consistent with necrotizing fasciitis. IV antibiotics were initiated and additional amputations consisting of 2<sup>nd</sup> and 3<sup>rd</sup> digits and metatarsal heads with removal of all necrotic tissue were performed. Once infection was controlled, negative pressure wound therapy was started.

Approximately 1 week later the residual dorsal wound measured 7.4 cm x 3.0 cm x 5.1 cm with exposed 2<sup>nd</sup> metatarsal bone. A second wound located plantarly over the 2<sup>nd</sup> and 3<sup>rd</sup> metatarsal area was present and measured 2.3 cm 3.2 cm x 1 cm and partially communicated with the dorsal wound. A PalinGen® Hydromembrane application was applied in aseptic fashion to dorsal wound, overlying any exposed bone and capsule and fenestrated non-adherent dressing was layered over graft for protection. Plantar wound was dressed with aquacel and sterile dressing. Next, mechanically powered negative pressure wound therapy (SNaP®) was started. Weekly applications of the Hydromembrane to dorsal wound continued. At week #2 and week #5 post-op, the plantar wound was treated with 1.0 ml of PalinGen® Flow and by week #8 the plantar wound was considered healed. By week #7, any prior exposed bone was not visible and the base of the dorsal wound was 100% granular with wound measuring 4.5 cm x 3.0 cm x 2.0 cm. By week #11, percent area reduction was 96%. By week #19 wound measured 1.0 cm x 0.7 cm, markedly decrease in size and depth from initial presentation.



Figure 4



Figure 5



Figure 6



Figure 7



Figure 8



Figure 9



Figure 10

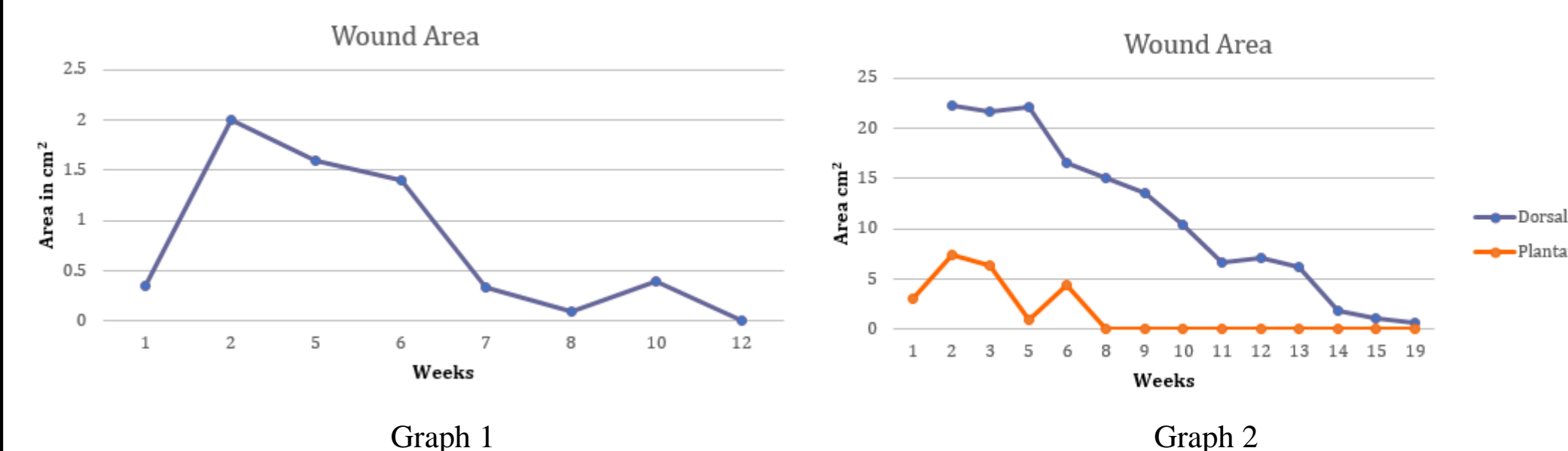


Figure 11

**Figures 4-10:** 4: Five days post initial application. 5: Application of SNaP® over hydromembrane. 6: Week #2 initial treatment with PalinGen® Flow to plantar wound 7: Week #5 of plantar wound & 2<sup>nd</sup> treatment with PalinGen® Flow. 8: Week #5 with no exposed bone and marked improvement in depth. 9: Week #8 plantar wound healed. 10: Week #11 with 96% percent area reduction. 11: Week #19.

## Results

In both cases, complete closures of non-healing surgical incision following diabetic amputations were observed after treated with the amniotic tissue allografts. In case 1, the wound treated with PalinGen® Hydromembrane continued to decrease and was fully healed at 12 weeks post amputation dehiscence. The patient remains infection free with limited scarring and has not had a recurrence of ulceration in over 30 days since closure. In case 2, the dorsal wound decreased by 96% after treatment with PalinGen® Hydromembrane over 11 weeks., while the plantar ulcer was completely epithelialized and healed after 2 implantations of PalinGen® Flow over 8 weeks. The plantar ulceration remains healed at week 19. Both patients had no adverse effects or recurrence of ulceration since closure.



**Graph 1:** Depicts Case 1 with healing accomplished by week 12.

**Graph2:** Depicts Case 2 with steady decrease in dorsal wound area and depth by week 19 healing accomplished of plantar wound by week 8.

## Conclusion

The results of the treatment indicate that both amnion membrane allograft and cryopreserved liquid amniotic allograft are safe to use and can support the healing of post-amputation wounds in patients with diabetes.

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